Department of Labor / Department of Health and Human Services

APPENDIX 5

JOINT ADVISORY NOTICE

Protection Against Occupational Exposure To Hepatitis B Virus (HBV) And Human Immunodeficiency Virus (HIV)

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I. Background:

Hepatitis B (previously called serum hepatitis) is the major infectious occupational health hazard in the health-care industry, and a model for the transmission of blood-borne pathogens. In 1985 the Centers for Disease Control (CDC) estimated [1] that there were over 200,000 cases of hepatitis B virus (HBV) infection in the U.S. each year, leading to 10,000 hospitalizations, 250 deaths due to fulminant hepatitis, 4,000 deaths due to hepatitis-related cirrhosis, and 800 deaths due to hepatitis-related primary liver cancer. More recently [2] the CDC estimated the total number of HBV infections to be 300,000 per year with corresponding increases in numbers of hepatitis-related hospitalizations and deaths. The incidence of reported clinical hepatitis B has been increasing in the United States, from 6.9/100,000 in 1978 to 9.2/100,000 in 1981 and 11.5/100,000 in 1985 [2]. The Hepatitis Branch, CDC, has estimated [unpublished] that 500-600 health-care workers whose job entails exposure to blood are hospitalized annually, with over 200 deaths (12-15 due to fulminant hepatitis, 170-200 from cirrhosis, and 40-50 from liver cancer). Studies indicate that 10% to 40% of health-care or dental workers may show serologic evidence of past or present HBV infection [3]. Health-care costs for hepatitis B and non-A, non-B hepatitis in health-care workers were estimated to be $10 - $12 million annually [4]. A safe, immunogenic, and effective vaccine to prevent hepatitis B has been available since 1982 and is recommended by the CDC for health-care workers exposed to blood and body fluids [1,2,5-7]. According to unpublished CDC estimates, approximately 30-40% of health-care workers in high-risk settings have been vaccinated to date.

According to the most recent data available from the CDC [8], acquired immunodeficiency syndrome (AIDS) was the 13th leading cause of years of potential life lost (82,882 years) in 1984, increasing to 11th place in 1985 (152,595 years). As of August 10, 1987, a cumulative total of 40,051 AIDS cases (of which 558 were pediatric) had been reported to the CDC, with 23,165 (57.8%) of these known to have died [9]. Although occupational HIV infection has been documented [10], no AIDS case or AIDS-related death is believed to be occupationally related. Spending within the Public Health Service related to AIDS has also accelerated rapidly, from $5.6 million in 1982 to $494 million in 1987, with $791 million requested for 1988. Estimates of average lifetime costs for the care of an AIDS patient have varied considerably, but recent evidence suggests the amount is probably in the range of $50,000 to $75,000.

Infection with either HBV [1,2] or human immunodeficiency virus (HIV, previously called human T-lymphotrophic virus type III/lymphadenopathy-associated virus (HTLV III/LAV) or AIDS-associated retrovirus (ARV)) [11,12]

can lead to a number of life-threatening conditions, including cancer. Therefore, exposure to HBV and HIV should be reduced to the maximum extent feasible by engineering controls, work practices, and protective equipment. (Engineering controls are those methods that prevent or limit the potential for exposure at or as near as possible to the point of origin, for example by eliminating a hazard by substitution or by isolating the hazard from the work environment.)

II. Modes Of Transmission:

In the U.S., the major mode of HBV transmission is sexual, both homosexual and heterosexual. Also important is parenteral (entry into the body by a route other than the gastrointestinal tract) transmission by shared needles among intravenous drug abusers and to a lesser extent in needlestick injuries or other exposures of health-care workers to blood. HBV is not transmitted by casual contact, fecal-oral or airborne routes, or by contaminated food or drinking water [1,2,13]. Workers are at risk of HBV infection to the extent they are exposed to blood and other body fluids; employment without that exposure, even in a hospital, carries no greater risk than that for the general population [1]. Thus, the high incidence of HBV infection in some clinical settings is particularly unfortunate because the modes of transmission are well known and readily interrupted by attention to work practices and protective equipment, and because transmission can be prevented by vaccination of those without serologic evidence of previous infection.

Identified risk factors for HIV transmission are essentially identical to those for HBV. Homosexual/bisexual males and male intravenous drug abusers account for 85.4% of all AIDS cases, female intravenous drug abusers for 3.4%, and heterosexual contact for 3.8% [9]. Blood transfusion and treatment of hemophilia/coagulation disorders account for 3.0% of cases, and 1.4% are pediatric cases. In only 3.0% of all AIDS cases has a risk factor not been identified [9]. Like HBV, there is no evidence that HIV is transmitted by casual contact, fecal-oral or airborne routes, or by contaminated food or drinking water [12-14], and barriers to HBV are effective against HIV. Workers are at risk of HIV infection to the extent they are directly exposed to blood and body fluids. Even in groups that presumably have high potential exposure to HIV-contaminated fluids and tissues, e.g., health-care workers specializing in treatment of AIDS patients and the parents, spouse, children, or other persons living with AIDS patients, transmission is recognized as occurring only between sexual partners or as a consequence of mucous membrane or parenteral (including open wound) exposure to blood or other body fluids [10,11,13-16].

Despite the similarities in the modes of transmission, the risk of HBV infection in health-care settings far exceeds that for HIV infection [13,14]. For example, it has been estimated [14,17,18] that the risk of acquiring HBV infection following puncture with a needle contaminated by an HBV carrier ranges from 6% to 30%—far in excess of the risk of HIV infection under similar circumstances, which the CDC and others estimated to be a less than 1% [10,13,16].

Health-care workers with documented percutaneous or mucous-membrane exposures to blood or body fluids of HIV-infected patients have

been prospectively evaluated to determine the risk of infection after such exposures. As of June 30, 1987, 883 health-care workers have been tested for antibody to HIV in an ongoing surveillance project conducted by CDC [19]. Of these, 708 (80%) had percutaneous exposures to blood, and 175 (20%) had a mucous membrane or an open wound contaminated by blood or body fluid. Of 396 health-care workers, each of whom had only a convalescent-phase serum sample obtained and tested 90 days or more post-exposure, one—for whom heterosexual transmission could not be ruled out—was seropositive for HIV antibody. For 425 additional health-care workers, both acute- and convalescent-phase serum samples were obtained and tested; none of 74 health-care workers with nonpercutaneous exposures seroconverted, and three (0.9%) of 351 with percutaneous exposures seroconverted. None of these three health-care workers had other documented risk factors for infection.

Two other prospective studies to assess the risk of nosocomial acquisition of HIV infection for health-care workers are ongoing in the United States. As of April 30, 1987, 332 health-care workers with a total to 453 needlestick or mucous-membrane exposures to the blood or other body fluids of HIV-infected patients were tested for HIV antibody at the National Institutes of Health [20]. These exposed workers included 103 with needlestick injuries and 229 with mucous-membrane exposures; none had seroconverted. A similar study at the University of California of 129 health-care workers with documented needlestick injuries or mucous-membrane exposures to blood or other body fluids from patients with HIV infection has not identified any seroconversions [21]. Results of a prospective study in the United Kingdom identified no evidence of transmission among 150 health-care workers with parenteral or mucous-membrane exposure to blood or other body fluids, secretions, or excretions from patients with HIV infection [22].

Following needlestick injuries, one health-care worker contracted HBV but not HIV, and in another instance a health-care worker contracted cryptococcus but not HIV from patients infected with both [14]. This risk of infection by HIV and other blood-borne pathogens for which immunization is not available extends to all health-care workers exposed to blood, even those who have been immunized against HBV infection. Effective protection against blood-borne disease requires universal observation of common barrier precautions by all workers with potential exposure to blood, body fluids, and tissues [10,13].

HIV has been isolated from blood, semen, saliva, tears, urine, vaginal secretions, cerebrospinal fluid, breast milk, and amniotic fluid [10,23], but only blood and blood products, semen, vaginal secretions, and possibly breast milk (this needs to be confirmed) have been directly linked to transmission of HIV [10,13]. Contact with fluids such as saliva and tears has not been shown to result in infection [13-15]. Although other fluids have not been shown to transmit infection, all body fluids and tissues should be regarded as potentially contaminated by HBV or HIV, and treated as if they were infectious. Both HBV and HIV appear to be incapable of penetrating intact skin, but infection may result from infectious fluids coming into contact with mucous membranes or open wounds (including inapparent lesions) on the skin [14,16]. If a procedure involves the potential for skin contact with

blood or mucous membranes, then appropriate barriers to skin contact should be worn, e.g., gloves. Investigations of HBV risks associated with dental and other procedures that might produce particulates in air, e.g., centrifuging and dialysis, indicated that the particulates generated were relatively large droplets (spatter), and not true aerosols of suspended particulates that would represent a risk of inhalation exposure [24-26]. Thus, if there is the potential for splashes or spatter of blood or fluids, face shields or protective eyewear and surgical masks should be worn. Detailed protective measures for health-care workers have been addressed by the CDC [10,13,23,27-33]. These can serve as general guides for the specific groups covered, and for the development of comparable procedures in other working environments.

HIV infection is known to have been transmitted by organ transplants [34] and blood transfusions [35] received from persons who were HIV seronegative at the time of donation. Falsely negative serology can be due to improperly performed tests or other laboratory error, or testing in that "window" of time during which a recently infected person is infective but has not yet converted from seronegative to seropositive. (Detectable levels of antibodies usually develop within 6 to 12 weeks of infection [36]. A recent report [37] suggesting that this "window" may extend to 14 months is not consistent with other data, and therefore requires confirmation.) If all body fluids and tissues are treated as infectious, no additional level of worker protection will be gained by identifying seropositive patients or workers. Conversely, if worker protection and work practices were upgraded only following the return of positive HBV or HIV serology, then workers would be inadequately protected during the time required for testing. By producing a false sense of safety with "silent" HBV- or HIV-positive patients, a seronegative test may significantly reduce the level of routine vigilance and result in virus exposure. Furthermore, developing, implementing, and administering a program of routine testing would shift resources and energy away from efforts to assure compliance with infection control procedures. Therefore, routine screening of workers or patients for HIV antibodies will not substantially increase the level of protection for workers above that achieved by adherence to strict infection control procedures.

On the other hand, workers who have had parenteral exposure to fluids or tissues may wish to know whether their own antibody status converts from negative to positive. Such a monitoring program can lead to prophylactic interventions in the case of HBV infection, and CDC has published guidelines on pre- and post-exposure prophylaxis of viral hepatitis [1,2]. Future developments may also allow effective intervention in the case of HIV infection. For the present, post-exposure monitoring for HIV at least can release the affected worker from unnecessary emotional stress if infection did not occur, or allow the affected worker to protect sexual partners in the event infection is detected [10,36].

III. Summary:

The cumulative epidemiologic data indicate that transmission of HBV and HIV requires direct, intimate contact with or parenteral inoculation of blood and blood products, semen, or tissues [10,11,13,14,16,23]. The mere pres-

ence of, or casual contact with, an infected person cannot be construed as "exposure" to HBV or HIV. Although the theoretical possibility of rare or low-risk alternative modes of transmission cannot be totally excluded, the only documented occupational risks of HBV and HIV infection are associated with parenteral (including open wound) and mucous membrane exposure to blood and tissues [2,10,13,14,16]. Workers occupationally exposed to blood, body fluids, or tissues can be protected from the recognized risks of HBV and HIV infection by imposing barriers in the form of engineering controls, work practices, and protective equipment that are readily available, commonly used, and minimally intrusive.

IV. Recommendations:

General

"Exposure" (or "potential exposure") to HBV and HIV should be defined in terms of actual (or potential) skin, mucous membrane, or parenteral contact with blood, body fluids, and tissues. "Tissues" and "fluids" or "body fluids" should be understood to designate not only those materials from humans, but also potentially infectious fluids and tissues associated with laboratory investigations of HBV or HIV, e.g., organs and excreta from experimental animals, embryonated eggs, tissue or cell cultures and culture media, etc.

As the first step in determining what actions are required to protect worker health, every employer should evaluate all working conditions and the specific tasks that workers are expected to encounter as a consequence of employment. That evaluation should lead to the classification of work-related tasks to one of three categories of potential exposure (Table 1). These categories represent those tasks that require protective equipment to be worn during the task (Category I); tasks that do not require any protective equipment (Category III); and an intermediate grouping of tasks (Category II) that also do not require protective equipment, but that inherently include the predictable job-related requirement to perform Category I tasks unexpectedly or on short notice, so that these persons should have immediate access to some minimal set of protective devices. For example, law enforcement personnel or firefighters may be called upon to perform or assist in first aid or to be potentially exposed in some other way. This exposure classification applies to tasks rather than to individuals, who in the course of their daily activities may move from one exposure category to another as they perform various tasks.

For individual Category I and II tasks, engineering controls, work practices, and protective equipment should be selected after careful consideration, for each specific situation, of the overall risk associated with the task. Factors that should be included in that evaluation of risk include:

1. Type of body fluid with which there will or may be contact (e.g., blood is of greater concern than urine),
2. Volume of blood or body fluid likely to be encountered (e.g., hip replacement surgery can be very bloody while corneal transplantation is almost bloodless),

3. Probability of an exposure taking place (e.g., drawing blood will more likely lead to exposure to blood than will performing a physical examination),
4. Probable route of exposure (e.g., needlestick injuries are of greater concern than contact with soiled linens), and
5. Virus concentration in the fluid or tissue. The number of viruses per milliliter of fluid in research laboratory cultures may be orders of magnitude higher than in blood. Similarly, viruses have been less frequently found in fluids such as sweat, tears, urine, and saliva.

Engineering controls, work practices, and protective equipment appropriate to the task being performed are critical to minimize HBV and HIV exposure and to prevent infection. Adequate protection can be assured only if the appropriate controls and equipment are provided and all workers know the applicable work practices and how to properly use the required controls or protective equipment. Therefore, employers should establish a detailed work practices program that includes standard operating procedures (SOPs) for all tasks or work areas having the potential for exposure to fluids or tissues, and a worker education program to assure familiarity with work practices and the ability to use properly the controls and equipment provided.

It is essential for both the patient and the health-care worker to be fully aware of the reasons for the preventive measures used. The health-care worker may incorrectly interpret the work practices and protective equipment as signifying that a task is unsafe. The patient may incorrectly interpret the work practices or protective garb as evidence that the health-care

TABLE 1. EXPOSURE CATEGORIES

CATEGORY I. Tasks That Involve Exposure To Blood, Body Fluids, Or Tissues.

All procedures or other job-related tasks that involve an inherent potential for mucous membrane or skin contact with blood, body fluids, or tissues, or a potential for spills or splashes of them, are Category I tasks. Use of appropriate protective measures should be required for every employee engaged in Category I tasks.

CATEGORY II. Tasks That Involve No Exposure To Blood, Body Fluids, Or Tissues, But Employment May Require Performing Unplanned Category I Tasks.

The normal work routine involves no exposure to blood, body fluids, or tissues, but exposure or potential exposure may be required as a condition of employment. Appropriate protective measures should be readily available to every employee engaged in Category II tasks.

CATEGORY III. Tasks That Involve No Exposure To Blood, Body Fluids, Or Tissues, And Category I Tasks Are Not A Condition Of Employment.

The normal work routine involves no exposure to blood, body fluids, or tissues (although situations can be imagined or hypothesized under which anyone, anywhere, might encounter potential exposure to body fluids). Persons who perform these duties are not called upon as part of their employment to perform or assist in emergency medical care or first aid or to be potentially exposed in some other way. Tasks that involve handling of implements or utensils, use of public or shared bathroom facilities or telephones, and personal contacts such as handshaking are Category III tasks.

provider knows or believes the patient is infected with HBV or HIV. Therefore, worker education programs should strive to allow workers (and to the extent feasible, the clients or patients) to recognize the routine use of appropriate work practices and protective equipment as prudent steps that protect the health of all.

If the employer determines that Category I and II tasks do not exist in the workplace, then no specific personal hygiene or protective measures are required. However, these employers should ensure that workers are aware of the risk factors associated with transmission of HBV and HIV so that they can recognize situations which pose increased potential for exposure to HBV or HIV (Category I tasks) and know how to avoid or minimize personal risk. A comparable level of education is necessary for all citizens. Educational materials such as the Surgeon General's Report can provide much of the needed information [12,38].

If the employer determines that work-related Category I or II tasks exist, then the following procedures should be implemented.

Administrative

The employer should establish formal procedures to ensure that Category I and II tasks are properly identified, SOPs are developed, and employees who must perform these tasks are adequately trained and protected. If responsibility for implementation of these responsibilities is delegated to a committee, it should include both management and worker representatives. Administrative activities to enhance worker protection include:

1. Evaluating the workplace to:
   a. Establish category of risk classifications for all routine and reasonably anticipated job-related tasks.
   b. Identify all workers whose employment requires performance of Category I or II tasks.
   c. Determine for identified Category I or II tasks those body fluids to which workers most probably will be exposed and the potential extent and route of exposure.
2. Developing, or supervising the development of, Standard Operating Procedures (SOPs) for each Category I and II task. These SOPs should include mandatory work practices and protective equipment for each Category I and II task.
3. Monitoring the effectiveness of work practices and protective equipment. This includes:
   a. Surveillance of the workplace to ensure that required work practices are observed and that protective clothing and equipment are provided and properly used.
   b. Investigation of known or suspected parenteral exposures to body fluids or tissues to establish the conditions surrounding the exposure and to improve training, work practices, or protective equipment to prevent a recurrence.

Training and Education

The employer should establish an initial and periodic training program for all employees who perform Category I and II tasks. No worker should engage in any Category I or II task before receiving training pertaining to the SOPs, work practices, and protective equipment required for that task. The training program should ensure that all workers:

1. Understand the modes of transmission of HBV and HIV.
2. Can recognize and differentiate Category I and II tasks.
3. Know the types of protective clothing and equipment generally appropriate for Category I and II tasks, and understand the basis for selection of clothing and equipment.
4. Are familiar with appropriate actions to take and persons to contact if unplanned Category I tasks are encountered.
5. Are familiar with and understand all the requirements for work practices and protective equipment specified in SOPs covering the tasks they perform.
6. Know where protective clothing and equipment is kept, how to use it properly, and how to remove, handle, decontaminate, and dispose of contaminated clothing or equipment.
7. Know and understand the limitations of protective clothing and equipment. For example, ordinary gloves offer no protection against needlestick injuries. Employers and workers should be on guard against a sense of security not warranted by the protective equipment being used.
8. Know the corrective actions to take in the event of spills or personal exposure to fluids or tissues, the appropriate reporting procedures, and the medical monitoring recommended in cases of suspected parenteral exposure.

Engineering Controls

Whenever possible, engineering controls should be used as the primary method to reduce worker exposure to harmful substances. The preferred approach in engineering controls is to use, to the fullest extent feasible, intrinsically safe substances, procedures, or devices. Substitution of a hazardous procedure or device with one that is less risky or harmful is an example of this approach, e.g., a laser scalpel reduces the risk of cuts and scrapes by eliminating the necessity to handle the conventional scalpel blade.

Isolation or containment of the hazard is an alternative engineering control technique. Disposable, puncture-resistant containers for used needles, blades, etc., isolate cut and needlestick injury hazards from the worker. Glove boxes, ventilated cabinets, or other enclosures for tissue homogenizers, sonicators, vortex mixers, etc. serve not only to isolate the hazard, but also to contain spills or splashes and prevent spatter and mist from reaching the worker.

After the potential for exposure has been minimized by engineering controls, further reductions can be achieved by work practices and, finally, personal protective equipment.

Work Practices

For all identified Category I and II tasks, the employer should have written, detailed Standard Operating Procedures (SOPs). All employees who perform Category I or II tasks should have ready access to the SOPs pertaining to those tasks.

1. Work practices should be developed on the assumption that all body fluids and tissues are infectious. General procedures to protect health-care workers against HBV or HIV transmission have been published elsewhere [1, 2, 23,28-33]. Each employer with Category I and II tasks in the workplace should incorporate those general recommendations, as appropriate, or equivalent procedures into work practices and SOPs. The importance of handwashing should be emphasized.
2. Work practices should include provision for safe collection of fluids and tissues and for disposal in accordance with applicable local, state, and federal regulations. Provision must be made for safe removal, handling, and disposal or decontamination of protective clothing and equipment, soiled linens, etc.
3. Work practices and SOPs should provide guidance on procedures to follow in the event of spills or personal exposure to fluids or tissues. These procedures should include instructions for personal and area decontamination as well as appropriate management or supervisory personnel to whom the incident should be reported.
4. Work practices should provide specific and detailed procedures to be observed with sharp objects, e.g., needles, scalpel blades. Puncture-resistant receptacles must be readily accessible for depositing these materials after use. These receptacles must be clearly marked and specific work practices provided to protect personnel responsible for disposing of them or processing their contents for reuse.

Personal Protective Equipment

Based upon the fluid or tissue to which there is potential exposure, the likelihood of exposure occurring, the potential volume of material, the probable route of exposure, and overall working conditions and job requirements, the employer should provide and maintain personal protective equipment appropriate to the specific requirements of each task.

For workers performing Category I tasks, a required minimum array of protective clothing or equipment should be specified by pertinent SOPs. All Category I tasks do not involve the same type or degree of risk, and therefore all do not require the same kind or extent of protection. Specific combinations of clothing and equipment must be tailored to specific tasks. Minimum levels of protection for Category I tasks in most cases would include use of appropriate gloves. If there is the potential for splashes, protective eyewear or face shields should be worn. Paramedics responding to an auto accident might protect against cuts on metal and glass by wearing gloves or gauntlets that are both puncture-resistant and impervious to blood. If the conditions of exposure include the potential for clothing becoming soaked with blood, protective outer garments such as impervious coveralls should be worn.

For workers performing Category II tasks, there should be ready access to appropriate protective equipment, e.g., gloves, protective eyewear, or surgi-

cal masks, specified in pertinent SOPs. Workers performing Category II tasks need not be wearing protective equipment, but they should be prepared to put on appropriate protective garb on short notice.

Medical

In addition to any health-care or surveillance required by other rules, regulations, or labor-management agreement, the employer should make available at no cost to the worker:

1. Voluntary HBV immunization for all workers whose employment requires them to perform Category I tasks and who test negative for HBV antibodies. Detailed recommendations for protecting health-care workers from viral hepatitis have been published by the CDC [1]. These recommendations include procedures for both pre- and post-exposure prophylaxis, and should be the basis for the routine approach by management to the prevention of occupational hepatitis B.
2. Monitoring, at the request of the worker, for HBV and HIV antibodies following known or suspected parenteral exposure to blood, body fluids, or tissues. This monitoring program must include appropriate provisions to protect the confidentiality of test results for all workers who may elect to participate.
3. Medical counseling for all workers found, as a result of the monitoring described above, to be seropositive for HBV or HIV. Counseling guidelines have been published by the Public Health Service [1, 2, 36].

Recordkeeping

If any employee is required to perform Category I or II tasks, the employer should maintain records documenting:

1. The administrative procedures used to classify job tasks. Records should describe the factors considered and outline the rationale for classification.
2. Copies of all SOPs for Category I and II tasks, and documentation of the administrative review and approval process through which each SOP passed.
3. Training records, indicating the dates of training sessions, the content of those training sessions along with the names of all persons conducting the training, and the names of all those receiving training.
4. The conditions observed in routine surveillance of the workplace for compliance with work practices and use of protective clothing or equipment. If noncompliance is noted, the conditions should be documented along with corrective actions taken.
5. The conditions associated with each incident of mucous membrane or parenteral exposure to body fluids or tissue, an evaluation of those conditions, and a description of any corrective measures taken to prevent a recurrence or other similar exposure.

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